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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,256	04/08/2004	Robbert Benner	2183.03-6420US	1851
24247	7590	01/15/2008		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER KIM, YUNSOO	
			ART UNIT 1644	PAPER NUMBER
			NOTIFICATION DATE 01/15/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

<b>Office Action Summary</b>	Application No. 10/821,256	Applicant(s) BENNER ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/23/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1, 3-8 and 10-14 are pending and are under consideration.
2. The IDS filed on 10/23/07 has been acknowledged.
3. In light of Applicants' amendments to the claims, the rejections of record have been withdrawn.
4. The following new rejection is set forth herein.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-8, 10-14 are rejected under 35 U.S.C. 103 as being unpatentable over 2004/0013661 (IDS reference, of record), as evidenced by Merck Index (17<sup>th</sup> ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550, of record) and Merriam Webster's Dictionary (p. 82, of record) in view of Dwinnell et al., (Atlas of Diseases of Kidney, Ch. 12, 1999 of record) and U.S. Pat. No., 5,273,961, newly cited.

The '661 publication teaches a method of treating ischemia reperfusion injury by administration of pharmaceutical composition comprising synthetic immunoregulator AQGV in bolus (e.g. orally) or infusion (parenterally) with dose of 1-5 mg/kg bodyweight (abstract, claim 1, [0023], [0043-45], [0050], in particular) and the immunoregulator AQGV peptide is known to reduce production of NO, reducing BUN ([0047], in particular).

The '661 publication further teaches use of combination of immunoregulator ([0048]), use of diagnostic process to determine disease stage (claim 1) and the preparation of the peptide in PBS ([0051], in particular).

As is evidenced in Merck Index, p. 1145-46, 1847, the patient with renal failure has increased blood urea nitrogen in serum (p. 1845-1847, table), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845) as indication, symptoms and signs of renal failure.

"Bolus" is defined in Merriam-Webster's Medical Desk Dictionary as a rounded mass, soft mass of chewed food, thus it is extended to include oral administration.

The '661 publication does not explicitly teaches the method of treating acute renal failure with the administration of pharmaceutical composition comprising AQGV peptide.

However, Dwinnell et al. teaches that the patients with acute renal failure has high blood urea nitrogen concentration (Fig. 12.1-4, in particular).

The '961 patent teaches that the treatment of acute renal failure can be achieved by decreases of blood urea nitrogen (col. 12, under Example. in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ administration of AQGV composition as taught by the '661 publication in a method for treating acute renal failure by lowering a blood urea nitrogen concentration as taught by Dwinnell et al and the '961 patent.

One of the ordinary skill in the art would have been motivated to treat acute renal failure by administration AQGV peptide composition as taught by the '661 publication because the AQGV peptide is known to lower the blood urea nitrogen concentration and the lowering the blood urea nitrogen concentration is a well known method to treat acute renal failure as taught by Dwinnell and the '961 patent.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim is allowable.

8.. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

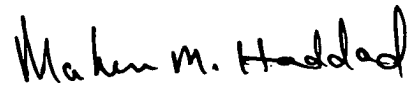
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Yunsoo Kim  
Patent Examiner  
Technology Center 1600  
January 3, 2008

A handwritten signature in black ink, reading "Maher M. Haddad". The signature is written in a cursive style with a large, stylized 'M' and 'H'.

MAHER M. HADDAD  
PRIMARY EXAMINER